



Rapid HIV Tests: Issues for Laboratorians

As of March 1998, the only rapid HIV test that is commercially available and licensed by the Food and Drug Administration (FDA) is the Single Use Diagnostic System for HIV-1 (SUDS), manufactured by Murex Corporation (Norcross, Georgia).^{*} Second-generation rapid HIV tests are being developed, and they may be licensed by the FDA in the future.

SUDS

- Licensed by FDA for clinical use in the United States
- Performed on serum or plasma (blood must be drawn from a vein)
- Classified as a test of moderate complexity, e.g., requires a laboratory with centrifuge
- Sensitivity and specificity similar to those of enzyme immunoassay (EIA)
- Results in 15 to 30 minutes
- Detects only HIV-1

Like the results of an EIA or any other screening test for HIV, reactive results from SUDS must be confirmed by a supplemental HIV test -- Western blot or immunofluorescence assay (IFA).

Several factors, including temperature and centrifuge speed, can affect test results.

Second-Generation Rapid HIV Tests

- None yet approved by the FDA
- Require little to no equipment
- Can be performed on serum, plasma, or whole blood, which can be collected by using the finger-stick method.

^{*}Use of trade names and commercial sources is for identification only and does not imply endorsement by the Public Health Service or the U.S. Department of Health and Human Services.

- Sensitivity and specificity similar to those of EIA
- Results in 2 to 5 minutes
- Detect HIV-1, HIV-2, and HIV-1 group O
- Make possible the application of the World Health Organization (WHO) strategy for combinations of two or more different rapid HIV tests to confirm a diagnosis of HIV infection. (This strategy has not been approved by the FDA for use in the United States.)

Costs of Rapid HIV Tests

- SUDS costs \$6 to \$10 per test kit
- Second-generation test costs estimated at \$2 to \$10 per test kit

Interpretation of Rapid HIV Test Results

Interpretation is the same as for any HIV screening test. Negative results from a single rapid HIV test do not require confirmation. Reactive results must be confirmed by a supplemental HIV antibody test. At this time, confirmation is done with Western blot or IFA.